K090954
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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

JUL 30 2009

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of ATLAS Wound Matrix.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 30, 2009
Contact Person:	Ryan M. Belaney Sr. Regulatory Affairs Specialist/Product Development Engineer
Proprietary Name:	ATLAS Wound Matrix
Common Name:	Animal-derived, extra-cellular matrix wound care product
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	General and Plastic Surgery/KGN

DEVICE INFORMATION

A. INTENDED USE

The ATLAS Wound Matrix devices intended use is for the management of wounds including:

- partial and full thickness wounds,
- pressure ulcers,
- venous ulcers,
- diabetic ulcers,
- chronic vascular ulcers,
- tunneled/undermined wounds,
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears),
- draining wounds.

The device is supplied sterile and is intended for one-time use.

B. DEVICE DESCRIPTION

The design features of the ATLAS Wound Matrix are substantially equivalent to the design features of the predicate devices. A brief description of the ATLAS Wound Matrix is provided below.

IMPLANT DESCRIPTION

The ATLAS Wound Matrix is a sterile, decellularized fenestrated or non-fenestrated processed porcine collagen dermal material. The material, which is rehydrated at the time of implant, is designed to be thin enough to conform to the wound it will cover. The matrix material will be made available in a variety of sizes depending on surgical use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the ATLAS Wound Matrix are substantially equivalent to the previously cleared predicates. Additionally, the safety and effectiveness of the ATLAS Wound Matrix is adequately supported by the substantial equivalent information and materials data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 9 2009

Wright Medical Technology, Inc.
% Mr. Ryan Belaney
Biologics Development Engineer
5677 Airline Road
Arlington, Tennessee 38002

Re: K090954
Trade/Device Name: ATLAS Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 1, 2009
Received: July 2, 2009

Dear Mr. Belaney:

This letter corrects our substantially equivalent letter of July 30, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090954

Device Name: ATLAS Wound Matrix

Indications For Use:

The ATLAS Wound Matrix is intended for the management of wounds including:

- partial and full thickness wounds,
- pressure ulcers,
- venous ulcers,
- diabetic ulcers,
- chronic vascular ulcers,
- tunneled/undermined wounds,
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears),
- draining wounds.

The ATLAS Wound Matrix is a collagen wound dressing that provides an environment that supports wound healing.

The device is supplied sterile and is intended for one-time use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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